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Human Research Ethics Policy – Research Involving Human Participants

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Mana Whakaae | Approval Authority	Deputy Vice-Chancellor Research
Āpiha Whakapā | Contact Officer	Chair, Human Research Ethics Committee

Kupu Whakataki | Introduction

This document sets out the guiding principles and procedural matters to be followed when applying to the Human Research Ethics Committee (HREC).

Kaupapa Here | Policy Statements

The purpose of much research is to produce evolving understanding and information which may improve the situation of human beings. To undertake research involving human participants:

1. All research involving human participants should be conducted in accordance with ethical norms and be subject to ethical appraisal and approval of both its means and ends.

2. Researchers are responsible for ensuring their projects meet the demands of current best practice research ethics in their scholarly field.

3. It is the researcher's responsibility to bring to the ethics review their knowledge of their research and its ethical implications in their application as all research projects differ, so it is difficult for review committees to produce a one size fits all approach to their reviews. Research disciplines also often have their own research ethics literature.

4. It is the individual researcher's responsibility to determine whether their research falls under the scope of the national Health and Disability Ethics Committee (HDEC) review and provide evidence of this to the University if required (by means of an Out of Scope letter confirming that HDEC approval is not required).

Guiding Principles

Researchers and teachers must take account of the following principles when planning their projects and preparing their proposals. Where research varies from these principles a detailed justification must be included in the application.

1. Respect and Care for Persons

Informed consent

- Participation of a human subject in any research project, course work project, or teaching exercise must be voluntary and not obtained through coercion of any sort, or inducement beyond reasonable acknowledgement or compensation for participation.
- Information provided to gain the consent of participants must be both adequate and appropriate. Prospective participants must be made fully aware of the nature of the research, so that their decision to participate or not is adequately informed.
- Participants must also be made aware of their right to decline to participate in the research, and to withdraw from it at any time (including withdrawal of information they have provided).
- It is normally desirable that information be given, and consent obtained, in written form; but it is recognised that in certain cases this may not be appropriate or necessary. In these cases, the ethics of gaining consent through verbal or other communication should be discussed thoroughly in the application.
- Where a project involves solely an anonymous questionnaire, written consent need not be obtained provided that participants are clearly informed that completion of the questionnaire implies consent.
- In some research involving groups of persons, it may be necessary to obtain consent from leaders of the group, as well as from its members.
- Where prospective participants are not capable of giving informed consent to their own participation (as in the case of young children or persons with impairment or some disabilities), this must be obtained from other persons legally entitled to consent on behalf of the prospective participants.

Limitation of deception

- Deception of participants is allowable only when it is shown to be appropriate and necessary for the success of the project. Any deception or departure from the standard of **fully informed consent** must be justified in terms of its necessity to the scientific aims of the project.
- As soon as possible following completion of a project where deception has occurred, participants must be provided with an explanation of the true purpose of the project and of the need for the deception and should then be given the opportunity to withdraw from participation in the project.

Confidentiality

- Confidentiality of information is to be assured at all stages of a project; participants have an absolute right to privacy and confidentiality, and they must be invited to exercise this right.
- The identification of participants or use of information they provide must not occur without their consent, and steps must be taken to see that their identities cannot be known by unauthorised persons.
- In practical terms, researchers are responsible for the safekeeping of consent forms and the secure storage or destruction of information that may enable participants to be identified. Researchers should refer to terms and conditions as required by any funding agency that is wholly or partially funding the proposed research, the *Data Management Policy (PDF, 223KB)*, *Research Conduct Policy (PDF, 523KB)* and *Intellectual Property Policy (PDF, 538KB)* for more detailed information.
- Where transcription will be carried out by a person or persons other than the researcher a confidentiality agreement should be made with the transcribers and participants made aware of this.
- Projects must accord with legal requirements such as those of the *Privacy Act 2020 (New Zealand Legislation website)*. Researchers should refer to the *Privacy Policy (PDF, 761KB)* for the University's application of the Act.

Minimisation of harm to participants, groups or communities

- Researchers must endeavour to minimise any risks attendant on participation; such risks include pain, stress, emotional distress, embarrassment, and moral or cultural offence.
- Prospective participants must be informed of any potential risks at the time when informed consent is sought and should also be consulted to ascertain any potential risks they may foresee.
- Researchers also have an obligation to be available after participants have participated in the project should any stress, harm or other concerns arise.

Special care of potentially marginalised, or otherwise vulnerable or dis-empowered participants

- Research must demonstrate respect for the participant. It should be sensitive to the needs and characteristics of the participant(s), such as age, gender, sexuality, ethnicity, culture, religion, disability or social class.
- Researchers must recognise the power relationships involved in their work particularly where there are disparities related to age, race, culture, status, religion, class, gender or sexuality between researchers and participants, or where the persons involved belong to vulnerable groups in research such as young children, or people with mental illness or social disadvantage.

- When the participants in the research are children or other dependent persons, the following additional points should be observed:
    - The consent of the dependent persons must be obtained as far as possible; they must not be required to participate against their will.
    - The written informed consent of the legal guardians of persons who are in loco parentis (teachers, guardians, caregivers) must normally also be obtained, and in some cases the consent of legal guardians may be mandatory.

Respect for property rights, including intellectual property

- Researchers should respect the property of others. This covers legal rights to land, goods, and intellectual property as well as taonga and culturally sensitive data of any particular group.

2. Acknowledgement of Treaty of Waitangi

- The University is legally bound to acknowledge the principles of the Treaty of Waitangi in the performance of its functions and the exercise of its powers *(S 281(1)(b), Education and Training Act 2020 (New Zealand Legislation website)).*
- It is the responsibility of the researcher to be aware of when they should conduct consultation with Māori regarding their research. If in doubt the researcher should speak with their faculty Kaiārahi (Māori advisor), or Māori Research Kaiārahi in the Research & Innovation team.
- Consultation with Māori should be discussed through the Māori Research Kaiārahi. More information is available via *Māori Research (University Research and Innovation intranet) (Staff only)*
- All researchers, whether their research is health related or not, are referred to the *Health Research Council of New Zealand's Guidelines for Researchers on Health Research Involving Māori 2010 (Health Research Council of New Zealand website).*

3. Research Merit

- Projects involving human participants must be carried out and supervised by suitably qualified personnel.
- Research must meet appropriate scientific and scholarly standards.

4. Management of Conflicts of Interest

- Any real or possible conflicts of interest must be avoided or declared.

The Human Research Ethics Committee (HREC)

The Human Research Ethics Committee (HREC) is responsible to the Vice-Chancellor, via the Deputy Vice-Chancellor (Research) or his/her nominee.
Since 2012 the HREC reviews most health research under PhD level, and most other observational health research.

The role of the HREC is to

- support researchers, via review of researcher projects,
- to protect all participants in the research activity, including the researchers themselves, and
- to continually build the University's capability in research integrity.

Ethical standards do evolve but the focus of the Human Research Ethics Committee (HREC) is to review human subject research conducted by staff and students, and to ensure University research safeguards the dignity and welfare of human research subjects.

The HREC:

- Encourages all researchers to be aware of and seek guidance about the principles and values of ethical research involving human participants, particularly as those principles and values apply to their own fields of research.

- Reviews proposals for research and teaching exercises that involve human participants to ensure that this work is conducted with appropriate regard for ethical standards and cultural values. The HREC reviews all proposals that are conducted within the University or outside of the University from all schools and research units within the University.

- Endeavours to create a review process that grants researchers the same level of respect that researchers should offer to research participants.

There are occasions when publishers, funding agencies and other groups commissioning research require assurances that research projects have received ethical approval from an appropriate body. The HREC would provide such assurance.

Tikanga | Ethics Application Procedures

The Human Research Ethics Committee of the University of Canterbury (HREC), only accepts project applications for review from:

- Academic staff of the University of Canterbury
- Visiting academic staff
- Research Associates of the University of Canterbury, as endorsed by an academic staff member

- Students who are enrolled in a course of study at the University of Canterbury and who will carry out research under the supervision of, or in collaboration with, an academic staff member of the university
- The review process is treated like it is a conversation between the Researcher and the wider community (both within the University and the public) about how to best bring integrity to the research. The HREC represents the interests of the wider community.

Where research falls under the statutory regime of the Health and Disability Ethics Committees (HDECs) as set out in the New Zealand Public Health and Disability Act 2000 (New Zealand Legislation website), researchers do not need to also have their research reviewed by the HREC. However, they should send a copy of their approval and their final application to the University's HREC Ethics Coordinator for the University's records.

Projects requiring review may be initiated only after the appropriate committee has given its approval. Retrospective approval of projects that have already begun will not be granted.

Failure to gain approval may affect funding and publication decisions.

Projects which require ethical approval from the HREC

Include:

a) Any research or teaching activity in which **persons** are subjected to experimental procedures or observation or questioning or otherwise used as a source of information or data.

b) Research which draws on personal information which is not currently in the public domain accessed from artefacts such as documents or computer records that has been collected for other purposes than the research.

c) Projects not involving human participants, but that involve human tissue, genetic modification, or animals may also require review by an appropriate body. Researchers are expected to be aware of their responsibilities.

Low Risk Applications

These are applications involving the same risk as might be encountered in normal daily life.

Research may be considered low risk when it arises from

- Master's or PhD theses, or supervised projects undertaken as part of specific course requirements, where the theses or projects do not raise any issue of deception, threat, invasion of privacy, mental, physical or cultural risk or stress, and do not involve gathering personal information of a sensitive nature about or from individuals.

- Undergraduate and Honours class research projects which do not raise any issue of deception threat, invasion of privacy, mental, physical or cultural risk or stress, and do not involve gathering personal information of a sensitive nature about or from individuals, but do not have blanket approval as outlined below.

No project, regardless of level, will be considered as low risk if it involves any of the following:

- invasive physical procedures or potential for physical harm;
- procedures which might cause mental/emotional stress or distress, moral or cultural offence;
- personal or sensitive issues;
- potentially vulnerable, excluded, or marginalised groups;
- Tangata Whenua, whether Māori organisations, iwi, mana whenua or individuals;
- cross cultural research;
- investigation of illegal behaviour/s;
- invasion of privacy;
- collection of information that might be disadvantageous to the participant;
- use of information already collected that is not in the public arena which might be disadvantageous to the participant;
- use of information already collected which was collected under agreement of confidentiality;
- participants who are unable to give informed consent;
- where a conflict of interest exists, e.g., the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other relationship or power imbalance between the researcher and the research participants;
- deception;
- audio or visual recording without consent;
- withholding benefits from “control” groups;
- inducements; and/or
- risks to the researcher.

Note: This list is not exhaustive.

Blanket Approval

Blanket approval will be granted only for research projects that are low risk.

Blanket approval may be sought for undergraduate, graduate and postgraduate class research or projects related to specific courses and/or field trips, which pose no threat to the well-being of the participants and where the methodology and its ethical implications is similar for all the projects:

a) The staff member responsible for the project may seek approval for the whole class based on a single application to the appropriate committee in the first year.

b) This approval will be valid for three years if there is no substantial change in the project during this period. For the fourth year, a new application can be made seeking approval for a further three years and so on.

c) The staff member when applying, should set out how they are to ensure that the students

- who undertake those research projects are made fully aware of the need for and the requirement of seeking ethical approval for all research involving human participants;
- are conversant with the procedures involved in making such an application; and
- have completed a component of the course that involves a discussion of the research ethics involved in the class project.

Projects which do not require ethical approval

In some cases, research activities may not require the approval of the HREC and may be eligible for an exemption. In the first instance, those seeking an exemption need to contact the Committee.

If an exemption is agreed to, then responsibility for facilitating exempt activities rests with either the researcher (if a staff member), or with the responsible staff member (if a student). The exempt activities must conform to this policy. A letter will be issued from the HREC confirming the project details have been reviewed and found not to require ethical approval. Details will be held on file.

Insurance

The University retains insurance cover against claims relating to harm, loss or damage suffered by participants in research projects because of any negligent act, error or omission by or on behalf of the University. Where relevant, (e.g., for research involving human tissue), these words must be incorporated into consent forms:

"Where a person being a participant in research sanctioned by the University, suffers personal injury as a result of medical error or medical mishap, the injury may be considered for coverage under the accident compensation scheme, if the trial has had HREC approval."

Amendments to already approved research

Researchers often wish to make a change to their research project. Where researchers realise such a change will raise further ethical questions (e.g., a change in treatment of participants, or the way the data is handled), they should apply for an amendment. An email to the Ethics Coordinator, HREC requesting the amendment should include

- all details of the changes,
- any ethical issues that arise,
- a discussion of those ethical issues, and
- any public documents associated with the project (e.g., information sheets) that require revision as a result of the amendments.

Reconsideration of decisions of the Committee

An applicant who is dissatisfied with a decision of the HREC may request that the decision be reconsidered:

- Requests should be in writing and addressed to the Ethics Coordinator, HREC. Informal discussions of these matters may be initiated with members of the Committee.
- If approval is given for research, but there is deviation from the application, the approval may be withdrawn.
- In reconsidering the original decision, the Committee may seek and consider additional information.

  Complaints about research may be addressed to the HREC, the UC Research Committee, or the Deputy Vice-Chancellor (Research).

Monitoring of Quality of Ethics Review

Each year the HREC will work with universities across New Zealand to review its own internal processes and the quality of its reviews and will seek feedback from applicants about the helpfulness and quality of its reviews.

This should include but not be limited to

- a survey of all research staff at the University regarding ethical review of projects, and
- the moderation of four high risk applications by another University ethics review committee.

He kōrero anō | Related Documents and Information

Whakaturetanga | Legislation

- Accident Compensation Act 2001 (New Zealand Legislation website)

- Copyright Act 1994 (New Zealand Legislation website)
- Education and Training Act 2020 (New Zealand Legislation website)
- Health & Safety at Work Act 2015 (New Zealand Legislation website)
- Health Research Council Act 1990 (New Zealand Legislation website)
- Human Tissue Act 2008 (New Zealand Legislation website)
- New Zealand Bill of Rights Act 1990 (New Zealand Legislation website)
- New Zealand Public Health and Disability Act 2000 (New Zealand Legislation website)
- Privacy Act 2020 (New Zealand Legislation website)

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- Conflict of Interest Policy Principles and Guidelines (PDF, 605KB)
- Copyright Policy (PDF, 548KB)
- Data Management Policy (PDF, 228KB)
- Intellectual Property Policy (PDF, 538KB)
- Privacy Policy (PDF, 761KB)
- Research Conduct Policy (PDF, 514KB)

Te Pae Tukutuku me te Ipurangiroto o UC | UC Website and Intranet

- Māori Research (University Research & Innovation intranet) (Staff only)

Mōwaho | External

Health Research Council of New Zealand's Guidelines for Researchers on Health Research Involving Māori 2010 (HRC of New Zealand website)

Document History and Version Control Table			
Version	**Action**	**Approval Authority**	**Action Date**
For document history and versioning prior to 2013 contact ucpolicy@canterbury.ac.nz			
1.00	• Conversion of document onto new template and document pushed out. • AVC(R) changed to DVC(R) in line with current title • Hyperlinks updated	Policy Unit	Aug 2013
1.01	Document review date pushed out	Secretary, Human Ethics Committee	Feb 2014
1.02	Document review date pushed out.	Policy Unit	Feb 2014
1.03	• Removal of contact from Low Risk Applications • Hyperlinks updated	Secretary, Human Ethics Committee	Apr 2014
1.04	Review date pushed out.	Policy Unit	Oct 2014
1.05	Updated A/A title to Deputy Vice-Chancellor	Policy Unit	Sept 2017
2.00	Scheduled review, major changes to content	Deputy Vice-Chancellor	May 2018

3.00	Scheduled review by Contact Officer, minor changes only.	Policy Unit	Mar 2020
3.01	Name and content of policy changed to reflect merger of committees and amendment to wording regarding exemption, review date changed.	Deputy Vice-Chancellor Research	Nov 2021
3.02	Removal of the following sentence upon request from the Ethics Coordinator "*Projects which meet low risk criteria are firstly reviewed and approved by departments/schools, but also require a final review and approval by the appropriate committee*"	Policy Unit	April 2022

This policy remains in force until it is updated.